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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,576	05/24/2007	Gregory Royce Collier	007193-25 US	5096

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EXAMINER	
BETTON, TIMOTHY E	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
03/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,576	COLLIER ET AL.	
	Examiner	Art Unit	
	TIMOTHY E. BETTON	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-11 and 15-35 are drawn to a method for treating or preventing symptoms of obesity, anorexia, need of satiation, weight maintenance conditions, metabolic energy levels and/or inflammatory disease conditions in an animal said method comprising administering to said animal an effective amount of a compound selected from a calcium uptake inhibitor or promoter, a blocker or promoter of TRPV2 calcium channels and a biological dye which inhibits or promotes calcium uptake for a time and under conditions to ameliorate one or more symptoms.

Group II, claims 12-14 are drawn to pharmaceutical composition comprising an agent selected from the list as disclosed.

2. The invention of Group I and Group II are not related to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they do not possess the same or corresponding special technical features for the following reasons: Group I possesses methods and processes of use which share the same technical feature directed to method steps and process steps of use which are unified in view and scope of claimed invention. However, Group II is drawn to pharmaceutical compositions, compounds, and/or active agents as presented in combination formulation therapy which does not share the same technical feature with the claimed method steps and process of use steps. Additionally, the chemical agent disclosed in the instant claims as 1-[β-[3-(4-methoxyphenyl) propoxy]-4-methoxyphenethyl]-lH- imidazole is well-known in the art.

Research into the relative importance of receptor- *vs* store-operated mechanisms in smooth muscle excitation-contraction coupling has been hampered by the paucity of selective blocking drugs for the respective channels. SKF96365, (1-[β-[3-(4-methoxyphenyl) propoxy]-4-methoxy-phenethyl]-1H-imidazole hydrochloride) the most commonly used inhibitor of store-operated calcium entry, is one of a series of N_1-substituted imidazole compounds which also includes econazole and miconazole [...]. Certainly SKF96365 blocks the store-operated current in mouse anococcygeus cells [...] , but at a similar concentrations (IC_{50} approximately 10 μM) it also blocks the muscarinic receptor operated cation current in ileal smooth muscle [...] and

voltage-operated calcium channels in other tissues [...]. At higher concentrations, SKF96365 may also exert a range of other effects unrelated to its channel blocking activity [...]. Recently, we have found that another N_1-substituted imidazole, trifluoromethylphenylimidazole (TRIM), better known as an inhibitor of neuronal nitric oxide synthase [...], shows selectivity for store-operated calcium entry over voltage-operated calcium entry in mouse anococcygeus smooth muscle [...], though whether this selectivity extends to receptor-operated currents, and to other smooth muscle tissues, remains to be established McFadzean et al., The developing relationship between receptor-operated and store-operated calcium channels in smooth muscle, Br J Pharmacol. 2002 January; 135(1): 1–13. doi: 10.1038/sj.bjp.0704468, printed pages 1-24, especially page 10 of 24.

However, the concomitant administration with ruthenium red dye (tetradecaaminedi-m-oxotrihexaehloride or a trans (8C1) isomer or an enantiomer thereof, and an ammoniated ruthenium oxychloride or a steroisomer or enantiomer thereof. and salts, homologs, orthologs, analogs, isomers, enantiomers, derivatives and functional equivalents thereof) is not apparent in the art as a combination therapy in view of the scope of claimed invention. Therefore, the technical feature recited in claim 1 is not special. Accordingly, the groups are not so linked as to form a single general concept under PCT Rule 13.1

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A single and specific mechanoreceptor of claims 1, 2, and 3 and all claims dependent therefrom;

Specifically, applicants are required to adequately specify which mechanoreceptor(s) respond to an agent which is an agonist, antagonist, inhibitor of expression of a gene encoding a mechanoreceptor, and an agent drawn to the enhancing of expression tetradecaaminedi-m-oxotrihexaehloride or a trans (8C1) isomer or an enantiomer thereof respectively, and an ammoniated ruthenium oxychloride or a steroisomer or enantiomer thereof;

A single and specific subject from claims 6-10, (e.g. human);

A single and specific species of ruthenium red dye, (e.g., ammoniated ruthenium oxychloride). This also includes distinguishing further whether the specifically elected biological dye is a salt, homolog, analog, etc. Applicants' are required to elucidate this distinction in the election of the species of a ruthenium red dye.

Further, two method species are disclosed in instant claims 19 and 20, which incorporate the word *and* and *or,* respectively, in reference to what the compound is indicated to be comprised. Applicants are required to elect between the limitation as disclosed in instant claim 19 and the limitation as disclosed in instant claim 20, (e.g., The method of Claim 19 wherein the compound is .1-[13-[3-(4- methoxyphenyl)propoxy]-4-methoxyphenethyl]-lH-imidazole and a ruthenium red dye ***or*** a salt or isomer or enantiomer thereof.

A single, exact , and specific disease state or disorder as disclosed in instant claim 26 and all claims dependent, e.g., obesity (and no other associated conditions);

If an inflammatory condition is elected, however, the applicants are required to elect one, specific and exact condition drawn to inflammation, (e.g. CIDP).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).The claims are deemed to correspond to the species listed above in the following manner methods of implementing the different and distinct compounds.

The following claim(s) are generic: 1-35.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected

process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shengjun Wang/

Primary Examiner, Art Unit 1617

TEB